



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 22 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

The Honorable Lamar Smith
Chairman
Committee on Science, Space, and Technology
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your June 8, 2016, letter regarding the U.S. Environmental Protection Agency's involvement with hospital disinfectants, sterilants, and antimicrobial devices.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pesticide registration process, the EPA examines data submitted by registrants to determine potential risks associated with proposed products and their use. For public health products, efficacy is also assessed according to the claims proposed to be made for the particular product. Once pesticide registrations are granted, registrants are required to accurately and consistently formulate the pesticide product consistent with the registered formulation.

The EPA's Antimicrobial Testing Program ensures that the agency approved hospital disinfectants and tuberculocides continue to meet stringent efficacy standards after their registration. Products that do not meet agency standards are brought into compliance through regulatory or enforcement measures, including removal of hospital disinfectant or tuberculocidal claims from product labels, voluntary manufacturer cancellation of a product registration, and removal of products from the marketplace. As your letter mentions, the EPA's Office of Inspector General is conducting a review of the Antimicrobial Testing Program and we are cooperating with the Office of Inspector General as it undertakes its review.

In addition, the EPA's current focus on the statutorily mandated reregistration process will increase confidence in the efficacy data supporting hospital disinfectant and tuberculocidal product registrations. Since 2014, the EPA has issued more than 2,000 product Data Call-In Notices under FIFRA for antimicrobial pesticide products with public health related efficacy claims to ensure they are supported by acceptable efficacy data.

As mentioned above, the EPA can take enforcement action against companies selling or distributing noncompliant products, including the types of products described in your inquiry. The agency's National Program Manager Guidance for fiscal years 2016-2017 includes an

enforcement focus area addressing product integrity with an emphasis on product efficacy and misbranding, including statements that imply or express government endorsement or involve the use of government logos.¹ FIFRA provides the EPA with a number of enforcement options ranging from issuance of Notices of Warning and Stop Sale, Use, or Removal Orders to assessment of civil penalties.

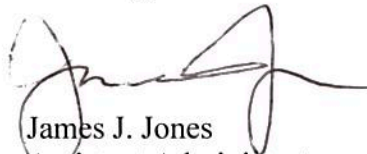
Your letter also asks about Safer Choice, the EPA's voluntary label program for advancing safer chemistry and chemical based products. More than 500 companies have partnered with Safer Choice to manufacture and label more than 2000 safer products. There are no Safer Choice labels on pesticides, including antimicrobial products, due to regulations prohibiting use of the term "safer" on pesticide products.²

To better inform the public about greener alternatives for pesticides products, the EPA has a pilot project for antimicrobials under the Design for the Environment (DfE) program. DfE, the former name of the Safer Choice program, is used for FIFRA regulated products to comply with the regulations mentioned above. Developed at the request of the agency's pesticides advisory committee, the pilot uses the DfE logo on qualifying antimicrobial products. Ensuring a product's efficacy is a required element of the agency's review of antimicrobial pesticides for the DfE program, so there is no compromise of efficacy under the DfE program. Since 2009, ten EPA registered antimicrobial products have received the DfE logo and none make safety claims. The EPA has spent less than one FTE annually on the DfE antimicrobials pilot project and has not used any extramural funding on the project.

Your letter requests specific associated documents and communications, and we have initiated the process of searching for these documents. Please be aware that this search is extensive since it involves checking with many EPA offices including in headquarters, at testing facilities and in each of the EPA's ten regional offices.

Again, thank you for your letter. Please feel free to contact me if you have any questions, or your staff may contact Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental Relations at kaiser.sven-erik@epa.gov or (202) 566-2753.

Sincerely,



James J. Jones
Assistant Administrator

Enclosures

cc: The Honorable Eddie Bernice Johnson
Ranking Member

¹ <https://www.epa.gov/planandbudget/national-program-manager-guidances#fy20162017>

² FIFRA section 2(q)(1)(A), 40 CFR 156.10(a)(5)